

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Pentobarbital Sodium / Phenytoin Formulation

Version 3.2 Revision Date: 30.09.2023 SDS Number: 9372657-00006 Date of last issue: 04.04.2023
Date of first issue: 27.08.2021

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Pentobarbital Sodium / Phenytoin Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-stance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
Walton Manor, Walton
MK7 7AJ Milton Keynes - United Kingdom

Telephone : +1-908-740-4000

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Flammable liquids, Category 3	H226: Flammable liquid and vapour.
Acute toxicity, Category 3	H301: Toxic if swallowed.
Skin sensitisation, Category 1	H317: May cause an allergic skin reaction.
Carcinogenicity, Category 2	H351: Suspected of causing cancer if swallowed.
Reproductive toxicity, Category 2	H361: Suspected of damaging fertility or the unborn child.
Specific target organ toxicity - single exposure, Category 1	H370: Causes damage to organs.
Specific target organ toxicity - repeated exposure, Category 2	H373: May cause damage to organs through prolonged or repeated exposure.
Long-term (chronic) aquatic hazard, Category 3	H412: Harmful to aquatic life with long lasting effects.

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2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Hazard pictograms	:	
Signal word	:	Danger
Hazard statements	:	H226 Flammable liquid and vapour. H301 Toxic if swallowed. H317 May cause an allergic skin reaction. H351 Suspected of causing cancer if swallowed. H361 Suspected of damaging fertility or the unborn child. H370 Causes damage to organs. H373 May cause damage to organs through prolonged or repeated exposure. H412 Harmful to aquatic life with long lasting effects.
Precautionary statements	:	Prevention: P201 Obtain special instructions before use. P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P273 Avoid release to the environment. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection. Response: P301 + P310 + P330 IF SWALLOWED: Immediately call a POISON CENTER/ doctor. Rinse mouth. P308 + P311 IF exposed or concerned: Call a POISON CENTER/ doctor.

Hazardous components which must be listed on the label:

Pentobarbital sodium
Phenytoin sodium
Benzyl alcohol

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.
Vapours may form explosive mixture with air.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

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Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Pentobarbital sodium	57-33-0 200-323-9	Acute Tox. 3; H301 Repr. 2; H361d STOT SE 1; H370 (Central nervous system) Aquatic Chronic 3; H412	>= 30 - < 50
Ethanol#	64-17-5 200-578-6 603-002-00-5	Flam. Liq. 2; H225 Eye Irrit. 2; H319 specific concentra- tion limit Eye Irrit. 2; H319 >= 50 %	>= 10 - < 20
Phenytoin sodium	630-93-3 211-148-2	Acute Tox. 3; H301 Skin Sens. 1; H317 Carc. 2; H351 Repr. 2; H361 STOT RE 1; H372 (Central nervous system)	>= 3 - < 10
Benzyl alcohol	100-51-6 202-859-9 603-057-00-5	Acute Tox. 4; H302 Acute Tox. 4; H332 Eye Irrit. 2; H319	>= 1 - < 10
Substances with a workplace exposure limit :			
Propylene glycol	57-55-6 200-338-0		>= 10 - < 20

For explanation of abbreviations see section 16.
#: Voluntarily-disclosed substance

SECTION 4: First aid measures

4.1 Description of first aid measures

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- If inhaled : If inhaled, remove to fresh air.
Get medical attention.

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- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.
- In case of eye contact : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.
Call a physician or poison control centre immediately.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

- Risks : Toxic if swallowed.
May cause an allergic skin reaction.
Suspected of causing cancer if swallowed.
Suspected of damaging fertility or the unborn child.
Causes damage to organs.
May cause damage to organs through prolonged or repeated exposure.

4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically and supportively.
-

SECTION 5: Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical
- Unsuitable extinguishing media : High volume water jet

5.2 Special hazards arising from the substance or mixture

- Specific hazards during fire-fighting : Do not use a solid water stream as it may scatter and spread fire.
Flash back possible over considerable distance.
Vapours may form explosive mixtures with air.
Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides
Nitrogen oxides (NO_x)
Metal oxides

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5.3 Advice for firefighters

- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
-

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

- Personal precautions : Remove all sources of ignition. Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

- Environmental precautions : Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

6.3 Methods and material for containment and cleaning up

- Methods for cleaning up : Non-sparking tools should be used. Soak up with inert absorbent material. Suppress (knock down) gases/vapours/mists with a water spray jet. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

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SECTION 7: Handling and storage

7.1 Precautions for safe handling

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
Use explosion-proof electrical, ventilating and lighting equipment.
- Advice on safe handling : Do not get on skin or clothing.
Do not breathe mist or vapours.
Do not swallow.
Avoid contact with eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Non-sparking tools should be used.
Keep container tightly closed.
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
Take precautionary measures against static discharges.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Contaminated work clothing should not be allowed out of the workplace.
Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

- Requirements for storage areas and containers : Keep in properly labelled containers. Store locked up. Keep tightly closed. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations. Keep away from heat and sources of ignition.
- Advice on common storage : Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Flammable solids
Pyrophoric liquids
Pyrophoric solids
Self-heating substances and mixtures
Substances and mixtures, which in contact with water, emit flammable gases

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Explosives
Gases
Very acutely toxic substances and mixtures

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Pentobarbital sodium	57-33-0	TWA	40µg/m ³ (OEB3)	Internal
		Wipe limit	400µg/100cm ²	Internal
Propylene glycol	57-55-6	TWA (Total vapour and particles)	150 ppm 474 mg/m ³	GB EH40
		TWA (particles)	10 mg/m ³	GB EH40
Ethanol	64-17-5	TWA	1,000 ppm 1,920 mg/m ³	GB EH40
Phenytoin sodium	630-93-3	TWA	50 µg/m ³ (OEB3)	Internal
		Wipe limit	500 µg/100 cm ²	Internal

Derived No Effect Level (DNEL):

Substance name	End Use	Exposure routes	Potential health effects	Value
Propylene glycol	Workers	Inhalation	Long-term local effects	10 mg/m ³
		Inhalation	Long-term systemic effects	168 mg/m ³
	Consumers	Inhalation	Long-term local effects	10 mg/m ³
		Inhalation	Long-term systemic effects	50 mg/m ³
	Ethanol	Workers	Inhalation	Long-term systemic effects
Skin contact			Long-term systemic effects	343 mg/kg bw/day
Consumers		Inhalation	Long-term systemic effects	114 mg/m ³
		Skin contact	Long-term systemic effects	206 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	87 mg/kg bw/day
Benzyl alcohol	Workers	Inhalation	Long-term systemic effects	22 mg/m ³

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	Workers	Inhalation	Acute systemic effects	110 mg/m ³
	Workers	Skin contact	Long-term systemic effects	8 mg/kg bw/day
	Workers	Skin contact	Acute systemic effects	40 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	5.4 mg/m ³
	Consumers	Inhalation	Acute systemic effects	27 mg/m ³
	Consumers	Skin contact	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Skin contact	Acute systemic effects	20 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Ingestion	Acute systemic effects	20 mg/kg bw/day

Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
Propylene glycol	Fresh water	260 mg/l
	Freshwater - intermittent	183 mg/l
	Marine water	26 mg/l
	Sewage treatment plant	20000 mg/l
	Fresh water sediment	572 mg/kg dry weight (d.w.)
	Marine sediment	57.2 mg/kg dry weight (d.w.)
	Soil	50 mg/kg dry weight (d.w.)
Ethanol	Fresh water	0.96 mg/l
	Freshwater - intermittent	2.75 mg/l
	Marine water	0.79 mg/l
	Sewage treatment plant	580 mg/l
	Fresh water sediment	3.6 mg/kg dry weight (d.w.)
	Marine sediment	2.9 mg/kg dry weight (d.w.)
	Soil	0.63 mg/kg dry weight (d.w.)
	Oral (Secondary Poisoning)	380 mg/kg food
Benzyl alcohol	Fresh water	1 mg/l
	Marine water	0.1 mg/l
	Intermittent use/release	2.3 mg/l
	Sewage treatment plant	39 mg/l
	Fresh water sediment	5.27 mg/kg
	Marine sediment	0.527 mg/kg
	Soil	0.456 mg/kg

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8.2 Exposure controls

Engineering measures

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

Use explosion-proof electrical, ventilating and lighting equipment.

Personal protective equipment

Eye/face protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Hand protection	:	
Material	:	Chemical-resistant gloves
Remarks	:	Consider double gloving. Take note that the product is flammable, which may impact the selection of hand protection.
Skin and body protection	:	Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to BS EN 14387
Filter type	:	Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	:	liquid
Colour	:	pink
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	44 - 60 °C

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Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

9.2 Other information

Flammability (liquids)	:	Not applicable
Molecular weight	:	No data available
Particle size	:	No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

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Hazardous reactions : Flammable liquid and vapour.
Vapours may form explosive mixture with air.
Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Toxic if swallowed.

Product:

Acute oral toxicity : Acute toxicity estimate: 261.96 mg/kg
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Components:

Pentobarbital sodium:

Acute oral toxicity : LD50 (Rat): 118 mg/kg
LD50 (Mouse): 239 mg/kg
LD50 (Rabbit): 175 mg/kg
LD50 (Dog): 65 mg/kg

Ethanol:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): 124.7 mg/l
Exposure time: 4 h

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Test atmosphere: vapour

Phenytoin sodium:

Acute oral toxicity : Acute toxicity estimate: 100 mg/kg
Method: Expert judgement

Benzyl alcohol:

Acute oral toxicity : LD50 (Rat): 1,620 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 4.178 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403

Propylene glycol:

Acute oral toxicity : LD50 (Rat): 22,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 44.9 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

Skin corrosion/irritation

Not classified based on available information.

Components:

Ethanol:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Benzyl alcohol:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Propylene glycol:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

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Components:

Ethanol:

Species : Rabbit
Method : OECD Test Guideline 405
Result : Irritation to eyes, reversing within 21 days

Benzyl alcohol:

Species : Rabbit
Method : OECD Test Guideline 405
Result : Irritation to eyes, reversing within 21 days

Propylene glycol:

Species : Rabbit
Method : OECD Test Guideline 405
Result : No eye irritation

Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

Components:

Ethanol:

Test Type : Local lymph node assay (LLNA)
Exposure routes : Skin contact
Species : Mouse
Result : negative

Phenytoin sodium:

Assessment : Probability or evidence of skin sensitisation in humans

Benzyl alcohol:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative

Propylene glycol:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Result : negative

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Germ cell mutagenicity

Not classified based on available information.

Components:

Ethanol:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test
Result: negative

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo : Test Type: Rodent dominant lethal test (germ cell) (in vivo)
Species: Mouse
Application Route: Ingestion
Result: equivocal

Phenytoin sodium:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro
Result: negative
Remarks: Based on data from similar materials

Test Type: In vitro sister chromatid exchange assay in mam-
malian cells
Result: positive
Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo
cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Benzyl alcohol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo
cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

Propylene glycol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

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Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

Carcinogenicity

Suspected of causing cancer if swallowed.

Components:

Phenytoin sodium:

Species : Rat
Application Route : Ingestion
Exposure time : 2 Years
Result : negative

Species : Mouse
Application Route : Ingestion
Exposure time : 2 Years
Result : positive

Carcinogenicity - Assessment : Limited evidence of carcinogenicity in animal studies (oral)

Benzyl alcohol:

Species : Mouse
Application Route : Ingestion
Exposure time : 103 weeks
Method : OECD Test Guideline 451
Result : negative

Propylene glycol:

Species : Rat
Application Route : Ingestion
Exposure time : 2 Years
Result : negative

Reproductive toxicity

Suspected of damaging fertility or the unborn child.

Components:

Pentobarbital sodium:

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

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Ethanol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Mouse
Application Route: Ingestion
Result: negative

Phenytoin sodium:

Effects on fertility : Test Type: reproductive and developmental toxicity study
Species: Rat
Application Route: Ingestion
Result: positive
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: reproductive and developmental toxicity study
Species: Rat
Application Route: Ingestion
Result: positive
Remarks: Based on data from similar materials

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, and/or on development, based on animal experiments.

Benzyl alcohol:

Effects on fertility : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development
Species: Mouse
Application Route: Ingestion
Result: negative

Propylene glycol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Mouse
Application Route: Ingestion
Result: negative

Effects on foetal development : Test Type: Embryo-foetal development
Species: Mouse
Application Route: Ingestion
Result: negative

STOT - single exposure

Causes damage to organs.

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Components:

Pentobarbital sodium:

Exposure routes : Ingestion
Target Organs : Central nervous system
Assessment : Causes damage to organs.

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:

Phenytoin sodium:

Exposure routes : Ingestion
Target Organs : Central nervous system
Assessment : Shown to produce significant health effects in animals at concentrations of 10 mg/kg bw or less.

Repeated dose toxicity

Components:

Ethanol:

Species : Rat
NOAEL : 1,280 mg/kg
LOAEL : 3,156 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Phenytoin sodium:

Species : Rat
NOAEL : > 100 mg/kg
Application Route : Ingestion
Exposure time : 13 Weeks
Remarks : Based on data from similar materials

Species : Mouse
NOAEL : > 10 - 100 mg/kg
LOAEL : > 10 - 100 mg/kg
Application Route : Ingestion
Exposure time : 13 Weeks
Remarks : Based on data from similar materials

Benzyl alcohol:

Species : Rat
NOAEL : 1.072 mg/l
Application Route : inhalation (dust/mist/fume)
Exposure time : 28 Days
Method : OECD Test Guideline 412

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Propylene glycol:

Species : Rat, male
NOAEL : $\geq 1,700$ mg/kg
Application Route : Ingestion
Exposure time : 2 yr

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Pentobarbital sodium:

Ingestion : Symptoms: dry mouth, mood swings, Dizziness, Headache, Nausea, central nervous system effects, Sweating

Phenytoin sodium:

Ingestion : Symptoms: Nausea, constipation, confusion, Vomiting, central nervous system effects, Dizziness, insomnia, Blood disorders, Liver disorders, Tremors, anorexia

SECTION 12: Ecological information

12.1 Toxicity

Components:

Pentobarbital sodium:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 49.5 mg/l
Exposure time: 96 h

Ethanol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): $> 1,000$ mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Ceriodaphnia (water flea)): $> 1,000$ mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : ErC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l
Exposure time: 72 h

EC10 (Chlorella vulgaris (Fresh water algae)): 11.5 mg/l
Exposure time: 72 h

Toxicity to microorganisms : EC50 (Pseudomonas putida): 6,500 mg/l
Exposure time: 16 h

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 9.6 mg/l
Exposure time: 9 d
Species: Daphnia magna (Water flea)

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Phenytoin sodium:

Toxicity to fish : EC50 (Danio rerio (zebra fish)): > 10 - 100 mg/l
Exposure time: 72 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : Remarks: No toxicity at the limit of solubility

Benzyl alcohol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 460 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 230 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 51 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

Propylene glycol:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to microorganisms : NOEC (Pseudomonas putida): > 20,000 mg/l
Exposure time: 18 h

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 13,020 mg/l
Exposure time: 7 d
Species: Ceriodaphnia dubia (water flea)

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12.2 Persistence and degradability

Components:

Ethanol:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 84 %
Exposure time: 20 d

Phenytoin sodium:

Biodegradability : Result: Not readily biodegradable.
Method: OECD Test Guideline 301C
Remarks: Based on data from similar materials

Benzyl alcohol:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 92 - 96 %
Exposure time: 14 d

Propylene glycol:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 98.3 %
Exposure time: 28 d
Method: OECD Test Guideline 301F

12.3 Bioaccumulative potential

Components:

Ethanol:

Partition coefficient: n-octanol/water : log Pow: -0.35

Phenytoin sodium:

Partition coefficient: n-octanol/water : log Pow: 2.84
Remarks: Calculation

Benzyl alcohol:

Partition coefficient: n-octanol/water : log Pow: 1.05

Propylene glycol:

Partition coefficient: n-octanol/water : log Pow: -1.07
Method: Regulation (EC) No. 440/2008, Annex, A.8

12.4 Mobility in soil

No data available

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12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal. Empty containers retain residue and can be dangerous. Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

ADN : UN 1993
ADR : UN 1993
RID : UN 1993
IMDG : UN 1993
IATA : UN 1993

14.2 UN proper shipping name

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ADN : FLAMMABLE LIQUID, N.O.S.
(Ethanol, Pentobarbital sodium)

ADR : FLAMMABLE LIQUID, N.O.S.
(Ethanol, Pentobarbital sodium)

RID : FLAMMABLE LIQUID, N.O.S.
(Ethanol, Pentobarbital sodium)

IMDG : FLAMMABLE LIQUID, N.O.S.
(Ethanol, Pentobarbital sodium)

IATA : Flammable liquid, n.o.s.
(Ethanol, Pentobarbital sodium)

14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADN	: 3	
ADR	: 3	
RID	: 3	
IMDG	: 3	
IATA	: 3	

14.4 Packing group

ADN
Packing group : III
Classification Code : F1
Hazard Identification Number : 30
Labels : 3

ADR
Packing group : III
Classification Code : F1
Hazard Identification Number : 30
Labels : 3
Tunnel restriction code : (D/E)

RID
Packing group : III
Classification Code : F1
Hazard Identification Number : 30
Labels : 3

IMDG
Packing group : III
Labels : 3
EmS Code : F-E, S-E

IATA (Cargo)
Packing instruction (cargo aircraft) : 366
Packing instruction (LQ) : Y344
Packing group : III

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Labels : Flammable Liquids

IATA (Passenger)

Packing instruction (passenger aircraft) : 355
Packing instruction (LQ) : Y344
Packing group : III
Labels : Flammable Liquids

14.5 Environmental hazards

ADN

Environmentally hazardous : no

ADR

Environmentally hazardous : no

RID

Environmentally hazardous : no

IMDG

Marine pollutant : no

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17) : Conditions of restriction for the following entries should be considered:
Number on list 3

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation : Not applicable

The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Brit-

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ain)

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

UK REACH List of substances subject to authorisation (Annex XIV) : Not applicable

GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation : Not applicable

Control of Major Accident Hazards Regulations 2015 (COMAH)

		Quantity 1	Quantity 2
H2	ACUTE TOXIC	50 t	200 t

P5c	FLAMMABLE LIQUIDS	5,000 t	50,000 t
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Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements

H225 : Highly flammable liquid and vapour.

H301 : Toxic if swallowed.

H302 : Harmful if swallowed.

H317 : May cause an allergic skin reaction.

H319 : Causes serious eye irritation.

H332 : Harmful if inhaled.

H351 : Suspected of causing cancer if swallowed.

H361 : Suspected of damaging fertility or the unborn child.

H361d : Suspected of damaging the unborn child.

H370 : Causes damage to organs.

H372 : Causes damage to organs through prolonged or repeated

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H412 : exposure.
: Harmful to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox. : Acute toxicity
Aquatic Chronic : Long-term (chronic) aquatic hazard
Carc. : Carcinogenicity
Eye Irrit. : Eye irritation
Flam. Liq. : Flammable liquids
Repr. : Reproductive toxicity
Skin Sens. : Skin sensitisation
STOT RE : Specific target organ toxicity - repeated exposure
STOT SE : Specific target organ toxicity - single exposure
GB EH40 : UK. EH40 WEL - Workplace Exposure Limits
GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECL - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

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Classification of the mixture:

Flam. Liq. 3	H226
Acute Tox. 3	H301
Skin Sens. 1	H317
Carc. 2	H351
Repr. 2	H361
STOT SE 1	H370
STOT RE 2	H373
Aquatic Chronic 3	H412

Classification procedure:

Based on product data or assessment
Calculation method
Calculation method
Calculation method
Calculation method
Calculation method
Calculation method
Calculation method

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

GB / EN